DEC 1 0 2002

Summary Information

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K023876

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1. Submitter name, address, contact	Ortho-Clinical Diagnostics, Inc. 100 Indigo Creek Drive Rochester, New York 14626-5101 (585) 453-4041 Contact Person: Marlene A. Hanna
2. Preparation date	Date Special 510(k) prepared: November 20, 2002
3. Device name	Trade or Proprietary Name: VITROS Chemistry Products Mg Slides VITROS Chemistry Products Calibrator Kit 1 Common Name : Magnesium test Classification Name: Magnesium test system (21 CFR 862.1495).
4. Predicate device	The VITROS Chemistry Products Mg Slides (modified) and VITROS Chemistry Products Calibrator Kit 1 are substantially equivalent to the VITROS Chemistry Products Mg Slides (current slide) and VITROS Chemistry Products Calibrator Kit 1.

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5. Device description

The VITROS Chemistry System uses *Vitros* Slides to perform discrete chemistry tests on body fluid specimens. All reactions necessary for a single quantitative measurement take place within the multi-layered analytical element of a *Vitros* Slide.

The system is comprised of two main elements:

1. The VITROS Chemistry Products range of chemistry products (in this case VITROS Chemistry Products Mg Slides, VITROS Chemistry Products Calibrator Kit 1, which are combined by the VITROS Chemistry System to perform the VITROS Mg test.

2. The VITROS Chemistry System – instrumentation, which provides automated use of the chemistry slides. Multiple VITROS Chemistry Systems were cleared for market by separate 510(k) pre-market notifications (K890928, K890929, K922072, K946090 and K922072).

The VITROS Chemistry System and Calibrators are dedicated specifically for use only with the VITROS Chemistry Products range of products.

6. Device intended use

VITROS Mg Slides
For in vitro diagnostic use only.
VITROS Mg Slides quantitatively measure Magnesium (MG) concentration in serum, plasma, and urine.

VITROS Calibrator Kit 1
For in vitro diagnostic use only.
VITROS Calibrator Kit 1 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of BUN/UREA, Ca, CREA, GLU, LAC, Li, Mg, PHOS, SALI, THEO, and URIC.

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7. Comparison to predicate device

The VITROS Chemistry Products Mg Slide (modified) and VITROS Chemistry Products Calibrator Kit 1 are substantially equivalent to VITROS Chemistry Products Mg Slide and VITROS Chemistry Products Calibrator Kit 1 that were cleared by the FDA for in vitro diagnostic use.
Mg Slide: (K861386, Cleared August 26, 1986)
Calibrator Kit 1: (K001885 Cleared July 20, 2000)

Table 1 lists the characteristics of the tests performed using the VITROS Mg Slide (modified) and the VITROS Mg Slide (current).

Table 1 List of Slide Characteristics: Comparison to Predicate Device

Device Characteristic	New Device VITROS Mg Slide (Modified)	Predicate Device VITROS Mg Slide (Current)
Sample volume	5 µL	10 µL
Quantity of Reactive Ingredients per slide (test)	1,2-bis(o-aminophenoxy)ethane-N,N,N',N'-tetraacetic acid (calcium chelator) 272.1 µg and 1,5-bis(2-hydroxy-3,5-dichlorophenyl)-3-cyanoformazan (dye) 46.19 µg	1,2-bis(o-aminophenoxy)ethane-N,N,N',N'-tetraacetic acid (calcium chelator) 542.3 µg and 1,5-bis(2-hydroxy-3,5-dichlorophenyl)-3-cyanoformazan (dye) 92.06 µg
Concentrations of Slide Reactive Ingredients per cm-squared	No Change.	1,2-bis(o-aminophenoxy)ethane-N,N,N',N'-tetraacetic acid (calcium chelator) 302.3 µg and 1,5-bis(2-hydroxy-3,5-dichlorophenyl)-3-cyanoformazan (dye) 51.32 µg
Intended Use	No change.	For in vitro diagnostic use only. VITROS Mg Slides quantitatively measure magnesium (Mg) concentration in serum, plasma and urine.
Basic principle	No Change.	Dry, multilayered slide utilizing reflectance spectrophotometry
Sample type	No Change.	Serum , plasma , urine
Reportable Range Serum,Plasma: Urine:	 No Change. No Change.	 0.20 – 10.00 mg/ dL 1.20 – 60.00 mg/dL (after multiplying by a 6X dilution factor)
Instrumentation	No Change.	VITROS 250, 500, 750 and 950 Series Analyzers
Incubation time and temperature	No Change.	Approximately 5 minutes at 37°C

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8. Conclusions

The information presented in the pre-market notification demonstrates that the performance of the VITROS Mg Slides (modified) for use with human serum, plasma, and urine is substantially equivalent to the cleared predicate device.

Equivalence was demonstrated using manufactured slides along with patient and quality control samples with measured Magnesium values spanning the assay range.

The information presented in the premarket notification provides a reasonable assurance that the VITROS Mg Slides (modified) for use with human serum, plasma, and urine is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 0 2002

Ms. Marlene A. Hanna
Regulatory Affairs Associate
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

Re: k023876
Trade/Device Name: VITROS Chemistry Products Mg Slides/
VITROS Chemistry Products Calibrator Kit 1
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIX; JGJ
Dated: November 20, 2002
Received: November 21, 2002

Dear Ms. Hanna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K023876

Device Name:
VITROS Chemistry Products Mg Slides
VITROS Chemistry Products Calibrator Kit 1

Intended Use:
VITROS Chemistry Products Mg Slides
For in vitro diagnostic use only.
VITROS Mg Slides quantitatively measure magnesium (Mg) concentration in serum, plasma, and urine.

VITROS Calibrator Kit 1
For in vitro diagnostic use only.
VITROS Calibrator Kit 1 is intended for use in calibration of the VITROS Chemistry Systems for the quantitative measurement of BUN/ UREA, Ca, CREA, GLU, LAC, Li, Mg, PHOS, SALI, THEO, and URIC.

Summary and Explanation of Test:
Magnesium is predominantly an intracellular cation and is essential in enzyme reactions. Magnesium deficiency may cause weakness, tremors, tetany, and convulsions. Hypomagnesemia is associated with hypocalcemia, alcoholism, some types of malnutrition, chronic hemodialysis, and pregnancy. Increased serum magnesium concentrations occur in patients with renal failure, dehydration, and Addison's disease.[1]

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper

(Divisi -Off)
Divisi inical Laboratory Devices
510(k) Number K023876

Prescription Use X OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)